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Patent

IN THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claim 1 (currently amended) A method for diagnosis of renal cell carcinoma (RCC) in a human, the method comprising the steps of:

- a) providing at least one peripheral blood sample of a human;
- b) generating an expression profile comprising expression levels of <u>two</u>one or more RCC disease genes in said at least one peripheral blood sample <u>of the human</u>;
- c) comparing the expression profile generated in step b) to at least one reference expression profile comprising expression levels of said twoene or more RCC disease genes wherein the reference expression profile is obtained from peripheral blood samples from patients having RCC and/or peripheral blood samples from disease-free humans, wherein differential expression of said two or more RCC genes in said the comparison is indicative of the presence or absence of RCC in the human; and

wherein said twoone or more RCC disease genes are selected from the group consisting, of eukaryotic elongation factor 1 alpha 2 (EEF1A2, SEQ ID NO:285); tolllike receptor 2 (TLR2, SEQ ID NO:1, SEQ ID NO:240); zinc finger protein 36, C3H tvpe-like 2 (BRF2, SEQ ID NO:286); lectin, galactoside-binding, soluble, 3 (LGALS3, SEQ ID NO:3); small nuclear ribonucleoprotein polypeptide G (SNRPG, SEQ ID NO:287); Ras-induced senescence 1 (DKFZP586E1621, SEQ ID NO:38); nuclear mitotic apparatus protein 1 (NUMA1, SEQ ID NO:288); superoxide dismutase 2 (SOD2, SEQ ID NO:248, SEQ ID NO:53); aldo-keto reductase family 1, member B1 (AKR1B1, SEQ ID NO:289); dual specificity phosphatase 6 (DUSP6, SEQ ID NO:241, SEQ ID NO:4); SWI/SNF related, matrix associated, actin dependent regulator of chromatin, subfamily e, member 1 (SMARCE1, SEQ ID NO:290, SEQ ID NO:328); KIAA0669 (SEQ ID NO:291); MLL septin-like fusion (MSF, SEQ ID NO:292); interleukin 1 receptor antagonist (IL1RN, SEQ ID NO:18); prothymosin, alpha (PTMA, SEQ ID NO:293); KIAA0410 (SEQ ID NO:294); proteasome 26S subunit, non-ATPase, 3 (PSMD3, SEQ ID NO:295); T54 protein (T54, SEQ ID NO:6); complement component 1, q subcomponent binding protein (C1QBP, SEQ ID NO:296); and oxidative-stress

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responsive 1 (OSR1, SEQ ID NO:297).

Claim 2 (Canceled)

Claim 3 (Previously presented) The method according to claim 1, wherein said peripheral blood sample comprises enriched peripheral blood mononuclear cells (PBMCs).

Claim 4 (Previously presented) The method according to claim 1, wherein said peripheral blood sample is a whole blood sample.

Claim 5 (Previously presented) The method according to claim 1, wherein the expression profile generated in step (b) is generated using quantitative RT-PCR or an immunoassay.

Claim 6 (Previously presented) The method according to claim 1, wherein said at least one reference expression profile comprises a reference expression profile comprising expression levels of said one or more RCC disease genes in peripheral blood samples of disease-free humans.

Claim 7 (Previously presented) The method according to claim 6, wherein said at least one reference expression profile further comprises a reference expression profile comprising expression levels of said one or more RCC disease genes in peripheral blood samples of patients having RCC.

Claim 8 (Currently amended) The method according to claim 7 wherein-said one or more RCC disease genes include at least two genes, and the expression profile generated in step (b) is compared to said at least one reference expression profile using a weighted voting algorithm.

Claims 9—20 (Canceled)

Claim 21 (Currently amended) The method according to claim 1, wherein said twoone or more RCC disease genes are TLR2 (SEQ ID NO:1, SEQ ID NO:240) and EEF1A2

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(SEQ ID NO:285).

Claim 22 (Currently amended) The method according to claim 1, wherein said two one or more RCC disease genes are TLR2 (SEQ ID NO:1, SEQ ID NO:240), LGALS3 (SEQ ID NO:3), EEF1A2 (SEQ ID NO:285), and BRF2 (SEQ ID NO:286).

Claim 23 (Currently amended) The method according to claim 1, wherein said two one or more RCC disease genes are TLR2 (SEQ ID NO:1, SEQ ID NO:240), LGALS3 (SEQ ID NO:3), DKFZP586E1621 (SEQ ID NO:38), EEF1A2 (SEQ ID NO:285), BRF2 (SEQ ID NO:286), and SNRPG (SEQ ID NO:287).

Claim 24 (Currently amended) The method according to claim 1, wherein said two one or more RCC disease genes are TLR2 (SEQ ID NO:1, SEQ ID NO:240), LGALS3 (SEQ ID NO:3), DKFZP586E1621 (SEQ ID NO:38), SOD2 (SEQ ID NO:248, SEQ ID NO:53), EEF1A2 (SEQ ID NO:285), BRF2 (SEQ ID NO:286), SNRPG (SEQ ID NO:287), and NUMA1 (SEQ ID NO:288).

Claim 25 (Currently amended) The method according to claim 1, wherein said two one or more RCC disease genes are TLR2 (SEQ ID NO:1, SEQ ID NO:240), LGALS3 (SEQ ID NO:3), DKFZP586E1621 (SEQ ID NO:38), SOD2 (SEQ ID NO:248, SEQ ID NO:53), DUSP6 (SEQ ID NO:241, SEQ ID NO:4), EEF1A2 (SEQ ID NO:285), BRF2 (SEQ ID NO:286), SNRPG (SEQ ID NO:287), NUMA1 (SEQ ID NO:288), and AKR1B1 (SEQ ID NO:289).

Claim 26 (Currently amended) The method according to claim 1, wherein said two ene or more RCC disease genes are TLR2 (SEQ ID NO:1, SEQ ID NO:240), LGALS3 (SEQ ID NO:3), DKFZP586E1621 (SEQ ID NO:38), SOD2 (SEQ ID NO:248, SEQ ID NO:53), DUSP6 (SEQ ID NO:241, SEQ ID NO:4), KIAA0669 (SEQ ID NO:291), EEF1A2 (SEQ ID NO:285), BRF2 (SEQ ID NO:286), SNRPG (SEQ ID NO:287), NUMA1 (SEQ ID NO:288), AKR1B1 (SEQ ID NO:289), and SMARCE1 (SEQ ID NO:290, SEQ ID NO:328).

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Claim 27 (Currently amended) The method according to claim 1, wherein said two one or more RCC disease genes are TLR2 (SEQ ID NO:1, SEQ ID NO:240), LGALS3 (SEQ ID NO:3), DKFZP586E1621 (SEQ ID NO:38), SOD2 (SEQ ID NO:248, SEQ ID NO:53), DUSP6 (SEQ ID NO:241, SEQ ID NO:4), KIAA0669 (SEQ ID NO:291), IL1RN (SEQ ID NO:18), EEF1A2 (SEQ ID NO:285), BRF2 (SEQ ID NO:286), SNRPG (SEQ ID NO:287), NUMA1 (SEQ ID NO:288), AKR1B1 (SEQ ID NO:289), SMARCE1 (SEQ ID NO:290, SEQ ID NO:328), and MSF (SEQ ID NO:292).

Claim 28 (Currently amended) The method according to claim 1, wherein said two one or more RCC disease genes are TLR2 (SEQ ID NO:1, SEQ ID NO:240), LGALS3 (SEQ ID NO:3), DKFZP586E1621 (SEQ ID NO:38), SOD2 (SEQ ID NO:248, SEQ ID NO:53), DUSP6 (SEQ ID NO:241, SEQ ID NO:4), KIAA0669 (SEQ ID NO:291), IL1RN (SEQ ID NO:18), KIAA0410 (SEQ ID NO:294), EEF1A2 (SEQ ID NO:285), BRF2 (SEQ ID NO:286), SNRPG (SEQ ID NO:287), NUMA1 (SEQ ID NO:288), AKR1B1 (SEQ ID NO:289), SMARCE1 (SEQ ID NO:290, SEQ ID NO:328), MSF (SEQ ID NO:292), and PTMA (SEQ ID NO:293).

Claim 29 (Currently amended) The method according to claim 1, wherein said two one or more RCC disease genes are TLR2 (SEQ ID NO:1, SEQ ID NO:240), LGALS3 (SEQ ID NO:3), DKFZP586E1621 (SEQ ID NO:38), SOD2 (SEQ ID NO:248, SEQ ID NO:53), DUSP6 (SEQ ID NO:241, SEQ ID NO:4), KIAA0669 (SEQ ID NO:291), IL1RN (SEQ ID NO:18), KIAA0410 (SEQ ID NO:294), T54 (SEQ ID NO:6), EEF1A2 (SEQ ID NO:285), BRF2 (SEQ ID NO:286), SNRPG (SEQ ID NO:287), NUMA1 (SEQ ID NO:288), AKR1B1 (SEQ ID NO:289), SMARCE1 (SEQ ID NO:290, SEQ ID NO:328), MSF (SEQ ID NO:292), PTMA (SEQ ID NO:293), and PSMD3 (SEQ ID NO:295).

Claim 30 (Currently amended) The method according to claim 1, wherein said two ene or more RCC disease genes are EEF1A2 (SEQ ID NO:285), TLR2 (SEQ ID NO:1, SEQ ID NO:240), BRF2 (SEQ ID NO:286), LGALS3 (SEQ ID NO:3), SNRPG (SEQ ID NO:287), DKFZP586E1621 (SEQ ID NO:38), NUMA1 (SEQ ID NO:288), SOD2 (SEQ ID NO:248, SEQ ID NO:53), AKR1B1 (SEQ ID NO:289), DUSP6 (SEQ ID NO:241, SEQ ID NO:4), SMARCE1 (SEQ ID NO:290, SEQ ID NO:328), KIAA0669 (SEQ ID NO:291), MSF (SEQ ID NO:292), IL1RN (SEQ ID NO:18), PTMA (SEQ ID NO:293),

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KIAA0410 (SEQ ID NO:294), PSMD3 (SEQ ID NO:295), T54 (SEQ ID NO:6), C1QBP (SEQ ID NO:296), and OSR1 (SEQ ID NO:297).